

Food and Drug Administration, HHS

§ 12.80

has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions;

(h) Rule on, admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 12.93;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any rule in this subpart under § 10.19 if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 12.45(e) or exclude any person from the hearing under § 12.90, or take other reasonable disciplinary action; and

(o) Take any action for the fair, expeditious, and orderly conduct of the hearing.

§ 12.75 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 12.97(b).

(b) A presiding officer who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 12.78 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commissioner will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Dockets Management Branch under § 10.20 except that only two copies need be filed. To determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by the Dockets Management Branch. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants. Submissions of documentary data and information are not required to be served on each participant, but any accompanying transmittal letter, pleading, summary, statement of position, certification under paragraph (d) of this section, or similar document must be served on each participant.

(c) Service is accomplished by mailing a submission to the address shown